IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

IN RE:	)
AREDIA and ZOMETA PRODUCTS	)
LIABILITY LITIGATION	)
	)
This Document Relates to Case Nos:	)
3:06-0388(Wilson)	) NO. 3:06-MD-1760
3:06-0389 (Fry)	) JUDGE CAMPBELL
3:06-0500 (Hillcoat)	)
3:06-0505 (Conklin)	)
3:06-0508 (Stoller)	)
3:06-0516 (King)	)
3:06-0527 (McKay)	)
3:06-0554 (Worthington)	)

MEMORANDUM

Pending before the Court is Defendant Novartis Pharmaceuticals Corporation's Motion for Partial Summary Judgment Regarding Lawsuits Filed by Certain Texas Plaintiffs (Docket No. 1380). Defendant asks the Court to dismiss the failure-to-warn claims of eight Plaintiffs, based upon a Texas statute which Defendant claims protects it from any products liability claims involving failure to provide adequate warnings if the drug at issue and accompanying warnings were approved by the U.S. Food and Drug Administration ("FDA"). For the reasons stated herein, Defendant's Motion is GRANTED.

SUMMARY JUDGMENT

Summary judgment "should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). In deciding a motion for summary judgment, the court must view the factual evidence and draw all reasonable

inferences in favor of the nonmoving party. Meyers v. Columbia/HCA Healthcare Corp., 341 F.3d 461, 466 (6th Cir. 2003); Hopson v. DaimlerChrysler Corp., 306 F.3d 427, 432 (6th Cir. 2002).

FACTS [1]

The parties do not dispute that the eight Plaintiffs involved in this Motion were citizens and residents of the State of Texas when these lawsuits were filed. With the exception of Plaintiff McKay, the Plaintiffs agree that their alleged injuries occurred in Texas. Plaintiff McKay asserts that no expert has opined as to when and where his injuries occurred, so it cannot be assumed that McKay's injuries occurred in Texas. Docket No. 1435-1, ¶ 40.

All Plaintiffs involved in this Motion filed their lawsuits in New York, except Plaintiff McKay, who filed his in Texas. All Plaintiffs included claims based, at least in part, on allegations that the warnings and other information provided by Defendant were inadequate. The drugs at issue in this case, Aredia and Zometa, were approved by the FDA.[2]

CHOICE OF LAW

Because the claims at issue are state law claims, the Court initially must determine which body of substantive law applies to each Plaintiff. To the extent a matter transferred pursuant to the multidistrict litigation statute concerns issues of state law, the Court must apply the state law that would have been applied to the individual cases had they not been transferred. In re Reciprocal of

[1] Defendant has failed to respond to Plaintiff McKay's statement of additional facts to which he contends there are genuine issues for trial (Docket No. 1435-1, p. 3).

[2] Plaintiffs' responses to Defendant's Statement of Undisputed Facts on this issue do not create a genuine issue of material fact for purposes of summary judgment. Docket No. 1434, ¶¶ 53-58.

America Sales Practice Litigation, 2006 WL 1699403 at *5 (W.D. Tenn. June 13, 2006); In re Rezulin Products Liability Litigation, 392 F. Supp 2d 597, 606 (S.D. N.Y. 2005).

For seven of the eight Plaintiffs, the Court will look to New York choice-of-law rules, because New York is the forum State for those actions. For Plaintiff McKay's lawsuit, the Court will look to Texas choice-of-law rules, since his action was filed in Texas.

Under New York choice-of-law rules, the substantive law of the state with the "greatest interest" applies. Rezulin, 392 F. Supp 2d at 612; Schultz v. Boy Scouts of America, 65 N.Y.2d 189, 197 (N.Y. 1985). Under this interest analysis, if conflicting conduct-relating laws are at issue, the law of the jurisdiction where the tort occurred will generally apply because that jurisdiction has the greatest interest in regulating behavior within its borders. Rezulin, 392 F.Supp. 2d at 612. The seven Plaintiffs who filed in New York do not dispute that Texas is the state with the "greatest interest" in this litigation.

Under Texas choice-of-laws rules, the law of the state with "the most significant relationship" to the litigation applies. Gutierrez v. Collins, 583 S.W.2d 312, 318 (Tex. 1979). Factual matters to consider in determining the state with the most significant relationship in a tort case include (1) the place where the injury occurred; (2) the place where the conduct causing the injury occurred; (3) the domicile, residence, nationality, place of incorporation and place of business of the parties; and (4) the place where the relationship, if any, between the parties is centered. Id. at 319; Perkins v. Dynasty Group Auto, 2003 WL 22810452 at * 3 (Tex. App. Nov. 25, 2003).

Defendant contends that the substantive law of Texas should apply to Plaintiff McKay's claims. Plaintiff McKay argues that where his injuries occurred is disputed and the Court cannot yet decide which substantive law should apply. Docket No. 1435, p. 7.

McKay asserts that he received some of his Aredia and Zometa doses in California, and his dentist is in Mexico. McKay does not dispute that he has lived in Texas since at least 1987. Docket No. 1435-1, ¶ 40. McKay does not dispute that numerous Texas physicians have evaluated and/or treated him for prostate cancer. Id. at ¶ 41. McKay also admits that several Texas physicians have prescribed and/or administered Aredia and/or Zometa to him. Id. at ¶ 42. McKay contends, however, that it is not clear what relative proportion of his infusions were administered or prescribed in Texas because he received some of them in California. Id.

Plaintiff McKay requests additional time in which to conduct discovery concerning which State has the most significant relationship to his claims and his injuries. The information concerning McKay's infusions, prescriptions and other treatments, however, is available to McKay without any need for formal discovery. Indeed, that information became available to McKay when the infusions, prescriptions and treatments occurred.

The issues concerning where and how Plaintiff McKay's injuries occurred involve information in the possession of McKay and his treating health care providers, and there has been no showing that anything prevented Plaintiff from obtaining that information before he filed this action or, more specifically, in response to Defendant's Motion. Accordingly, McKay's request for additional discovery is denied. McKay has not shown that, "for specified reasons," he "cannot present facts essential to justify his position" concerning the choice of substantive law applicable to his claims. Fed. R. Civ. P. 56(f).

For all these reasons, the Court finds that the substantive law of the State of Texas will apply to the failure-to-warn claims of the eight Plaintiffs involved in this Motion.

TEXAS STATUTE

The Texas statute upon which Defendant bases its Motion is Section 82.007 of the Texas Civil Practice and Remedies Code, which provides, in pertinent part:

> (a) In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:
>
> (1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act.

Tex. Civ. Prac. & Rem. Code Ann. § 82.007(a).

The statute then specifically explains how a claimant can rebut this presumption:

> (b) The claimant may rebut the presumption in Subsection (a) as to each defendant by establishing that:
>
> (1) the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury;

Tex. Civ. Prac. & Rem. Code Ann. § 82.007(b)(1).

Plaintiffs argue first that the Court should not exercise its authority to decide this Motion but, rather, should deny the Motion without prejudice so that it may be brought in the courts where these actions were originally filed. The Court declines this invitation.[3]

[3] Plaintiffs' request is entirely inconsistent with their earlier statements regarding amendments to the Case Management Order in these cases. There, Plaintiffs proposed that "all dispositive motions be heard by this Court prior to remand" because they were "concerned that a 'two step' process on general and fact specific dispositive motions, one before this court, and one before the remand court, will significantly delay trial in these matters." Docket No. 1327, p. 5.

Next, Plaintiffs contend that the Texas statute at issue is not preempted by federal law. Plaintiffs point out that the Texas statute, unlike the Michigan immunity statute previously at issue in this case[4] and at issue in the Garcia[5] case, simply creates a rebuttable presumption in favor of Defendant. Plaintiffs are correct that the language of the Texas statute specifically creates a rebuttable presumption that Defendant is not liable for failure-to-warn claims if the warnings provided with the product were approved by the FDA. In this way, the Texas statute does differ from the immunity statute in Michigan. If subsection (a) were the end of the statute, Plaintiffs' arguments would likely prevail.

The Texas Legislature, however, went on to establish certain evidentiary standards for rebutting this presumption. The statute provides, in subsection (b), limited and specific ways in which a claimant can rebut the presumption created by the statute in subsection (a). The presumption of adequate warnings, therefore, is unrebuttable unless one of the specific statutory provisions applies.

Neither side claims that any of the specifically enumerated ways to rebut the presumption applies in this instance except subsection (b)(1), so the Court need address only (b)(1). If Plaintiffs are precluded, by preemption or otherwise, from establishing the facts required under subsection (b)(1), Plaintiffs cannot rebut the presumption.[6]

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[4] See In re Aredia and Zometa Products Liability Litigation, 2008 WL 913087 (M.D. Tenn. April 2, 2008).

[5] Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961 (6th Cir. 2004) (holding as constitutional a Michigan statute immunizing drug manufacturers from products liability if the drug at issue was approved by the FDA).

[6] Plaintiff McKay argues that he can rebut the presumption, without invading the procedures of the FDA, by establishing that Defendant prevented information from reaching the global scientific and medical communities, but such a showing is not one of the ways Plaintiff can

In Buckman Co. v. Plaintiffs' Legal Comm., 121 S.Ct. 1012 (2001), the Court found that the plaintiffs' state law fraud-on-the-FDA claims conflicted with and were therefore impliedly preempted by the Federal Food, Drug and Cosmetic Act. Noting that policing fraud against federal agencies is hardly a "field which the States have traditionally occupied," the Court held that it is the FDA's exclusive responsibility to police fraud or wrongdoing in connection with approval of products before the FDA. Id. at 1017.[7]

The Court stated that fraud-on-the-FDA claims would "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." Id. at 1018. In sum, the Court opined, this sort of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore preempted by that scheme. Id. at 1020.

As stated above, in order to rebut the presumption under subsection (b)(1) in this case, Plaintiffs must establish that Defendant withheld or misrepresented "required information" to the FDA.[8] Because subsection (b)(1) concerns information submitted to the FDA, the "required information" reasonably would be information which is required to be submitted to the FDA

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rebut this presumption according to the statute. Such evidence might work if the statute did not include subsection (b), but it does.

[7] The relationship between a federal agency and the entity it regulates "is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." Buckman, 121 S.Ct. at 1017.

[8] By comparison, in order to overcome the immunity statute in Michigan, a plaintiff must show that the drug was not approved for safety and efficacy by the FDA and the drug and labeling were in compliance with the FDA's approval at the time the drug left the control of the manufacturer or seller. Garcia, 385 F.3d at 964. In Garcia, the Sixth Circuit found that any distinction between a cause of action for fraud on the FDA and the Michigan statutory exception was "immaterial in light of Buckman." Id. at 966.

pursuant to federal statute and regulations governing pharmaceutical products. The Court finds that the task of determining whether certain information was "required" by the FDA would raise the federalism concerns expressed in Buckman.

The Texas statute also requires that the information which was withheld or misrepresented be "material and relevant" to the performance of the product. Because subsection (b) concerns misrepresentations to the FDA, it is reasonable to infer that the information must be "material and relevant" to the FDA. Determining what information would have been important to the FDA would also create the federalism concerns noted by the Court in Buckman.

Finally, the information which was allegedly withheld or misrepresented must, under the Texas statute, be causally related to Plaintiffs' injuries. Unless the withheld information would have resulted in some definite change by the FDA, either non-approval of the drug or a labeling change, such withheld information could not be causally related to a plaintiff's injury. Again, in order to establish that the FDA would have acted differently if Defendant had submitted accurate information, Plaintiffs would have to "go behind" the FDA processes, raising the concerns sought to be avoided in Buckman.

Plaintiffs suggest that Ackermann v. Wyeth Pharmaceuticals, 471 F.Supp.2d 739 (E.D. Tex. 2006) dictates a finding of no preemption in this case. In an opinion adopted by the district judge in Ackermann, the magistrate judge stated: "Suffice to say, the Court believes that the language of section 82.007(a) creates nothing more than a presumption which the Defendant is free to raise. It does not create a cause of action where none existed before." Id. at 749.

However, subsection (b)(1) of this statute does not have to "create a cause of action" to be preempted. Subsection (b) limits the ways in which a plaintiff can rebut the presumption of

subsection (a). In order to pursue their failure-to-warn claims, Plaintiffs are required to prove that material and relevant information was withheld from the FDA. Whether that evidence is characterized as an element of Plaintiffs' proof or a "defense" to the presumption of this statute, the proof is the same. The federalism concerns of Buckman and Garcia are still present. The Court finds that requisite showing under the Texas statute is analogous to and sufficiently equivalent to asserting a claim of fraud on the FDA that the claim is preempted under Buckman.

CONCLUSION

For all these reasons, Defendant's Motion for Partial Summary Judgment Regarding Lawsuits Filed by Certain Texas Plaintiffs (Docket No. 1380) is GRANTED, and the claims of Plaintiffs Wilson, Fry, Hillcoat, Conklin, Stoller, King, McKay and Worthington which allege "failure to provide adequate warnings or information"[9] are DISMISSED.

IT IS SO ORDERED.

Todd Campbell

TODD J. CAMPBELL
UNITED STATES DISTRICT JUDGE

[9] Tex. Civ. Prac. & Rem. Code Ann. § 82.007(a).